

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR *DAUBERT*
MOTION TO EXCLUDE OR, IN THE ALTERNATIVE, TO LIMIT THE OPINIONS
AND TESTIMONY OF STEPHEN M. FACTOR, M.D.**

Plaintiffs in actions listed on attached Exhibit A, pursuant to Federal Rules of Evidence 702, 403, and 104, as well as the U.S. Supreme Court decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), hereby respectfully move this Court to exclude or limit certain opinions and testimony offered by the Defendants' expert Stephen M. Factor, M.D.

INTRODUCTION

The Defendants have designated Dr. Stephen Factor as an expert pathologist in the above-referenced cases. Dr. Factor is board certified in Anatomic and Clinical Pathology.¹ Dr. Factor's subspecialty is cardiovascular pathology and the bulk of his research, writing and teaching relate to cardiovascular pathology.² However, Dr. Factor attempts to offer certain opinions that are outside his area of expertise and are, therefore, inadmissible pursuant to Federal

¹ Exhibit B, Expert Report of Dr. Factor at p. 1.

² Exhibit C, 11/27/2012 Deposition of Dr. Factor at 17:18-18:16.

Rule of Civil Procedure (“Rule”) 702³ and *Daubert v. Merrell Dow Pharms. Inc.*^{4,5} Moreover, several of Dr. Factor’s opinions are not grounded in reliable principles or methods as required by *Daubert* and its progeny and must be excluded on that ground as well.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁶ The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.⁷

ARGUMENT

I. Dr. Factor Is Not Qualified To Render General Mesh Opinions, Including Opinions Concerning The Adequacy Of Mesh Design, Physical Characteristics Of The Mesh Or The Biocompatibility Of These Products.

Outside of his work as an expert in these cases, Dr. Factor has never analyzed a single explanted transvaginal polypropylene mesh device, has never performed any research whatsoever on mesh, has never published any articles or given any presentations on mesh, does not know what protocols are followed by pathologists who actually specialize in studying explanted surgical mesh devices, and does not hold himself out as expert on bridging fibrosis or

³ Rule 702 states that one must be qualified to proffer expert testimony by “knowledge, skill, experience training, or education.”

⁴ See *Daubert*, 509 U.S. 579 (1993).

⁵ See, e.g., *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs the admissibility of expert testimony).

⁶ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁷ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

scar plate formation and has never been trained by anybody professionally on how to identify these mesh-specific pathological features.^{8,9,10,11,12,13,14}

Dr. Factor's lack of experience with surgical meshes could not have been described any better than by Dr. Factor himself who testified as follows:

Q: You do not hold yourself out as an expert with regard to surgical mesh in particular, do you?

A: No.

Q: You do not hold yourself out with regard to the biocompatibility of surgical mesh; correct?

A: No.

Q: Meaning I'm correct?

A: Yes, you are correct.¹⁵

These issues go to the very heart of the claims and defenses in this litigation and, as such, experience in these areas is critical in order to provide any meaningful or reliable testimony at trial. Unfortunately, however, Dr. Factor offers numerous general opinions in his expert report that are beyond his expertise. For example, Dr. Factor renders opinions throughout his report

⁸ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 19:13-18 (Dr. Factor has never performed a pathological analysis of any explanted transvaginal mesh device outside of this litigation).

⁹ *Id.* at 22:9-13 (He has never published any articles related to polypropylene mesh).

¹⁰ *Id.* at 23:8-11 (He has never performed any research on surgical mesh).

¹¹ *Id.* at 22:14-17 (He has never given any presentations concerning mesh).

¹² Exhibit D, 3/5/2014 Deposition of Dr. Factor at 49:6-11 (Dr. Factor testified that he does not know what protocols are followed by pathologists who actually specialize in studying explanted surgical mesh devices).

¹³ Exhibit D, 3/5/2014 Deposition of Dr. Factor at 66:3-6; 66:16-24 (testified that he does not hold himself as an expert in bridging fibrosis or scar plate formation and has never been trained professionally on how to identify these pathologically).

¹⁴ Notably, this is in stark contrast to the experience of Dr. Iakovlev, who has devoted substantial practice to the review and analysis of explanted hernia and vaginal mesh products and who has published multiple peer-reviewed articles on these important topics.

¹⁵ Exhibit D, 3/5/2014 Deposition of Dr. Factor at 19:8-13

concerning the adequacy of the Prolene and Prolene Mesh design, including the physical properties of the mesh such as pore size, bridging fibrosis, scar platting, inflammation, degradation and shrinkage¹⁶ – opinions that Dr. Factor has already admitted are beyond the scope of his expertise.¹⁷ Tellingly, Dr. Factor has refused to render these types of opinions in prior cases:

Q: Doctor, are you going to be rendering any opinions on the size of the mesh pores?

A: No.¹⁸

Q: Do you have an opinion as to whether or not the mesh itself migrates within the female body?

A: I do not, no. I have no opinion.¹⁹

Q: Doctor, are you rendering an opinion in this case as to how the mesh works within the female body?

A: No.

Q: Do you have an understanding of how the mesh is intended to work within the female body?

¹⁶ See, e.g., Exhibit B, Expert Report of Dr. Factor at p. 8, 9, 14, 15, 17, 18, 19, 20, 21. See also Exhibit C, 11/27/2012 Deposition of Dr. Factor at 44:18-45:1.

¹⁷ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 44:18-45:1 (Dr. Factor admitted that he is not a bioengineer or mechanical engineer and is not an expert in these areas); 53:5-11 (Dr. Factor testified that he has no opinions concerning what happens to the mesh once it is placed in the female body; 44:14-17 (Dr. Factor testified that he has no opinions concerning how mesh is intended to work within the female body); Exhibit D, 3/5/2014 Deposition of Dr. Factor at 19:8-13 (Dr. Factor testified that he does not hold himself out as an expert on mesh or mesh biocompatibility).

¹⁸ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 50:8-11. See also *Id.* at 126:5-10.

¹⁹ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 75:12-16

A: Only in very broad senses. I mean, I'm not a bioengineer or mechanical engineer. I understand the general concept of support of tissues, but I'm not here as an expert in that area.²⁰

What little experience Dr. Factor does have in analyzing explanted polypropylene mesh specimens is limited to only eight to ten hernia mesh devices throughout his entire career.²¹ However, Dr. Factor testified that this limited experience cannot be extrapolated to other mesh devices globally, which would include Ethicon's transvaginally placed Prolene and Prolene Soft mesh products.²² Dr. Factor's experience in the field of anatomical and clinical pathology and vague notions of experience analyzing a handful of hernia mesh device does not automatically qualify him as an expert in pelvic mesh pathology and, without more, is insufficient to pass *Daubert* muster.

As one Court has noted,

both *Daubert* and *Kumho* make it clear that the day of the expert, who merely opines, and does so on basis of vague notions of experience, is over. Experts are now held to a level of accountability that requires factual predicates, in historical fact, or in competent evidence, which allows a factfinder to independently verify the accuracy of the expert's results. Absent such reliable verification, the expert's opinion is not admissible.

Solheim Farms, Inc. v. CHN America, LLC, 503 F.Supp.2d 1146, 1150 (D. Minn. 2007).

Opinions - like most of those offered by Dr. Factor - that flow neither from background nor research, that have no independent standing and are formed only for purposes of litigation should be excluded.²³

²⁰ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 44:18-45:1.

²¹ Exhibit C, 11/27/2012 Deposition of Dr. Factor at 19:19-20:21.

²² Exhibit C, 11/27/2012 Deposition of Dr. Factor at 63:23-65:8.

²³ *Daubert*, 43 F.3d at 1317 ("*Daubert II*"); see also *Lauzon v. Senco Prods., Inc.* 270 F.3d 681, 687 (8th Cir. 2001) (citing *Daubert II*, noting impetus for opinion as a factor in considering the admissibility of expert testimony); see also *Wagner v. Hesston Corp.*, 2005 WL 1540135 (D. Minn. June 30, 2005), at *6 (attached as Exhibit E) (citing *Daubert II*, noting that expert testing

Even if this Court determines that Dr. Factor is qualified to offer general opinions concerning the design, biocompatibility, or physical properties of the mesh, his deposition testimony demonstrates that the methods he uses to render these opinions are flawed:

Q: Is it fair to say that the materials that are significant to you in forming your opinion are the photomicrographs of the pathology specimens?

A: And the pathology slides.

Q: And the pathology slides?

A: Yes.

Q: You didn't base your opinions on the materials listed –

A: No.

Q: -- in this report, correct?

Q: There's some writings by Klinge and Klosterhalfen in this list of literature, this vast list of literature. Are those articles that you were familiar with?

A: I have not reviewed them from the time that I originally received them and read them. So I know their names. I don't know the content of what they said.

Q: Whatever they said was not of significance to you one way or the other in forming your opinions; correct?

A: Correct.²⁴

As this Court has noted, “[j]ust because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”²⁵ The admissibility of Dr. Factor’s

conducted almost entirely within the context of litigation “increase[d] the unreliability of [the expert’s] opinions”).

²⁴ Exhibit D, 3/5/2014 Deposition of Dr. Factor at 48:8-49:5

²⁵ *Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc.)*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).

unreliable and unfounded opinions presents a serious risk of confusing the issues and misleading the jury in this case and should be excluded.²⁶

II. By His Own Admission, Dr. Factor Is Not Qualified To Offer Reliable Opinion Testimony Concerning The Expected And Typical Inflammatory Response To Prolene and Prolene Mesh Devices Once Implanted In The Female Body.

Dr. Factor has testified that because of his inexperience in analyzing explanted vaginal mesh products, he does not know and is unable to offer any opinions concerning the expected inflammatory response to Ethicon's Prolene and Prolene Soft mesh devices once implanted in the female body:

Q: But can you quantify what is the expected inflammation; in other words, how bad or how severe that inflammation is in the typical female anatomy?

A: I would have to look at large numbers of specimens to be able to answer that and I can't answer that.

Q: So you don't have such an opinion?

A: Correct.²⁷

Yet, despite this admission, Dr. Factor opines in his expert report that the "inflammatory response associated with Prolene Soft is generally mild and is not essentially different than what would be expected if no mesh was employed."²⁸ As stated above, Dr. Factor has not undertaken the type of large-scale analysis of explanted Prolene and Prolene Soft mesh devices that – according to him – would be necessary to offer reliable opinions or testimony on this subject at trial. Thus, Dr. Factor should be excluded from offering this opinion at trial.

²⁶ See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'" (citing *Daubert*, 509 U.S. at 596)).

²⁷ Exhibit C, 11/27/2012 Deposition of Dr. Factor at at 65:24-66:13 (emphasis added).

²⁸ Exhibit B, Expert Report of Dr. Factor at p. 14.

III. Dr. Factor Is Not Qualified To Offer Opinions About Dr. Iakovlev's Methodology And Findings, Nor Is He Qualified To Opine On Whether Prolene And Prolene Soft Mesh Products Can Cause Pain In Patients

One primary focus of Dr. Factor's expert report is to criticize Dr. Iakovlev's methodology and findings relating to Prolene and Prolene Soft mesh and its ability to cause inflammation, bridging fibrosis, scarring, pain and also to undergo *in vivo* degradation. However, if the Court finds, as we believe it should, that Dr. Factor is unqualified to discuss these topics, as set forth above, he certainly is unqualified to criticize Dr. Iakovlev's studies and findings in this field and, therefore, should be precluded from offering these criticisms at trial. The pertinent question here is not whether or not Dr. Factor is right or wrong, and Plaintiffs do not need to challenge these opinions based on their accuracy.²⁹ As discussed in detail above, outside of his work as an expert in these cases, Dr. Factor has never analyzed a single explanted transvaginal polypropylene mesh device, has never performed any research whatsoever on mesh, has never published any articles or given any presentations on mesh, does not know what the typical inflammatory response is to Prolene and Prolene Soft mesh when implanted in the female body, does not know how the mesh was supposed to act after it was implanted, and does not know what protocols are followed by pathologists who actually specialize in studying explanted surgical mesh devices. Dr. Factor has admitted that he is not an expert in mesh, mesh biocompatibility, bridging fibrosis or scar plate formation and has never been trained by anybody professionally on how to identify these mesh-specific pathological features. As set forth in prior sections, Dr. Factor lacks the requisite knowledge, training and experience concerning mesh and should not be permitted to criticize Dr. Iakovlev.

²⁹ See *Westberry*, 178 F.3d at 261 (the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Factor is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. Factor's opinions, Ethicon cannot carry this burden and Dr. Factor's testimony should be excluded in its entirety.

Dated: April 21, 2016

Respectfully submitted,

/s/ Bryan F. Aylstock

Bryan F. Aylstock, Esq.

Renee Baggett, Esq.

Aylstock, Witkin, Kreis and Overholtz, PLC

17 East Main Street, Suite 200

Pensacola, Florida 32563

(850) 202-1010

(850) 916-7449 (fax)

rbaggett@awkolaw.com

baylstock@awkolaw.com

/s/Thomas P. Cartmell

Thomas P. Cartmell, Esq.

Jeffrey M. Kuntz, Esq.

Wagstaff & Cartmell LLP

4740 Grand Avenue, Suite 300

Kansas City, MO 64112

816-701-1102

Fax 816-531-2372

tcartmell@wcllp.com

jkuntz@wcllp.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com